REMARKS

In the Action, claims 1-7 and 9-31 are rejected, and claims 32-39 are withdrawn from consideration as being directed to the non-elected invention. In response, claims 1, 2, 5, 10, 11, 12, 19, 24, 26, 27-29 and 31 are amended, and new claims 40-43 are added. Claims 3, 30 and 32-39 are cancelled.

Claim 1 is amended to include the subject matter of claims 27 and 28. Support for these amendments is also found on page 7 in the third and fourth paragraphs. Specifically, claim 1 is amended to recite the interconnecting porous bioabsorbable inorganic bone regeneration material as calcium phosphate having a specific pore volume of 0.4 cm^3/g (0.4 ml/g) or more and a pore diameter of 0.1 to 500 μm and/or a particle size of 1 to 500 μm and/or a BET surface area of at least 0.1 m^2/g. The dependent claims are amended to be consistent with the amendments to claim 1 and to overcome the rejections under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

These amendments do not introduce new matter. The amendments to claim 1 incorporate the features of the dependent claims. Therefore, the claim amendments do not necessitate a new search so that any further action based on newly cited art should be made non-final.

The specification appears to be objected to based on matters of form, although no specific objection appears to be made. Applicants respectfully submit that the specification is in an acceptable format and that no amendments are needed at this time.

In view of these amendments and the following comments, reconsideration and allowance are requested.

Rejection Under 35 U.S.C. § 112

Claims 13 and 14 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Action suggests that the claims are not enabled by the specification because the specification does not teach a method of treatment.

The claims are not directed to a method of treatment as suggested in the Action. The claims are specifically directed to a method of producing a self-hardening bioabsorbable composite material. Claims 13 and 14, which depend from claim 1, recite a pharmaceutical active ingredient or mixture in the method of producing the bioabsorbable composite material. The specification clearly teaches one skilled in the art how to make the bioabsorbable composite material. Thus, the specification is enabling for the claimed method of producing the bioabsorbable composite material which contains an active ingredient. The comments in the Action regarding the treatment, prophylaxis or prevention of cancer and/or inflammation are not relevant to the enablement of the claimed method of producing the biocompatible composite material. Applicants respectfully submit that the specification is enabling for the claimed method.

Furthermore, the use of pharmaceutical additives in bioabsorbable materials is known in the art as disclosed in U.S. Patent No. 4,373,217 to Draenert, cited in the Action. Draenert discloses pharmacologically active agents in an implantation material. Thus, one of ordinary skill in the art has sufficient general knowledge which in combination with the specification enables the incorporation of a pharmaceutically active ingredient in a bioabsorbable composite material as in the claimed invention.

The claims are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The claims are amended to overcome these rejections noted in the Action.

In view of the above comments and the claim amendments, the claims are submitted to conform to 35 U.S.C. § 112, first and second paragraphs.

Rejection Under 35 U.S.C. § 102(b)

Claims 1-7, 9-11, 15, 18, 19, 21-26 and 28-31 are rejected under 35 U.S.C. § 102(b) as being anticipated by DE 199 39 403 to Schnabelrauch et al.

Claim 1 is amended to include the subject matter of original claim 27 to obviate this rejection. In addition, claim 1 is amended to recite a method of producing a self-hardening bioabsorbable composite material that includes calcium phosphate having a pore volume of 0.4 cm^3/g or more and at least one of a specifically defined pore diameter, particle size, and BET surface area. DE '403 does not disclose a method of producing a self-hardening bioabsorbable composite material from calcium phosphate having a pore volume, pore diameter, particle size and BET surface area within the ranges recited in amended claim 1. DE '403 is silent regarding these features. DE '403 does not disclose a porosity of the material either expressly or inherently. Thus, the features of amended claim 1 are not disclosed in DE '403 either expressly or inherently.

In view of these amendments and the above comments, independent claim 1 and the claims depending therefrom are not anticipated by DE '403.

Rejections Under 35 U.S.C. § 103(a)

Claims 17 and 20 are rejected under 35 U.S.C. § 103(a) as being obvious over DE '403. Claims 12-14, 16, 24, 27 and 28 are rejected as being obvious over the combination of DE '403 and U.S. Patent No. 4,373,217 to Draenert. As noted in the Action, DE '403 and Draenert do not disclose every feature of the claimed invention. The rejection is based on the

position that the features that are missing from the cited patents would have been obvious to one of ordinary skill in the art.

For the reasons discussed below, Applicants submit that DE '403 and Draenert either standing alone or in combination provide no teaching or suggestion to one skilled in the art to modify the process of Draenert and DE '403 as suggested in the Action. The claimed invention is not obvious over the cited patents where neither of the cited patents disclose or reasonably suggest each feature of the claimed invention.

As recognized in the Action, DE '403 does not disclose the claimed process of producing a self-hardening bioabsorbable composite material using calcium phosphate having the claimed pore volume, pore diameter, particle size and BET surface area. Draenert is not directed to a bioabsorbable composite material as in the claimed invention. Moreover, Draenert clearly does not disclose or suggest to one skilled in the art a bioabsorbable composite material containing calcium phosphate with a pore volume of 0.4 cm^3/g or more and the claimed pore diameter, particle size and BET surface area. Draenert expressly requires the calcium phosphate to have a pore volume of less than 0.1 ml/g.

The present invention is based on the surprising discovery that porous materials used in a fully bioabsorbable composition have advantages over the use of non-porous materials such as those used in the prior processes and the cited patents. The porous materials of the claimed invention enable the growth of cells into the cavities of the material which result in better adhesion and anchoring of bone cells and provide a direct bonding between the bone tissue and the bioabsorbable composite material at the interface without the formation of an interlayer of connective tissue. As a result, the porous materials exhibit a faster integration into the bone tissue. The porous structure of the biodegradable inorganic fillers of the bioabsorbable composite material enable the control of loading with the polymerization

initiator and activator over a wide concentration range, thereby obtaining higher loading capacities compared to non-porous filler materials.

The porous biodegradable materials of the present invention containing an in situ hardening polymer and a resorbable bioinorganic filler have a faster rate of biodegradation due to the larger surface area of the materials. The pores of the resorbable bioinorganic filler of the claimed invention are accessible to degrading media such as water, dissolved salts and enzymes, thereby enabling the bone regeneration material to be resorbed faster. The porosity of the filler material is an important aspect of the invention to improve and accelerate the biodegradation of the bioabsorbable composite material as a whole as a result of the polymers generated by the in situ hardening of the polymerizable monomers that have comparatively low degradation rates.

As noted above, DE '403 does not disclose or suggest to one skilled in the art a calcium phosphate having a pore volume of 0.4 cm^3/g or more as highly interconnected porous bioabsorbable inorganic bone regeneration materials. As disclosed on page 3, lines 3 and 4 for DE '403, the pore system of DE '403 is created under *in vivo* conditions by the resorption of the inorganic filler while at the same time the crosslinked matrix is conserved. Thus, the pores in the system of DE '403 are formed by the resorption of the inorganic material and not by the porosity of an inorganic material as in the claimed invention. One skilled in the art in reviewing DE '403 would readily conclude that the fillers of DE '403 are non-porous. Only by the complete degradation of the inorganic filler do the pores develop in the polymer matrix of DE '403.

DE '403 consistently suggests to one skilled in the art that the inorganic filler is non-porous by disclosing that the polymerization activator and polymerization initiator are applied as coatings on the surface of the filler materials and that the composite material should be mechanically workable after curing thereby allowing the formation of pores by

drilling or other mechanical means. In contrast, the claimed invention specifically defines the presence of interconnecting pores in the calcium phosphate having a specifically defined pore volume and pore diameter. These features are not disclosed or suggested in DE '403.

Draenert does not provide the deficiencies of DE '403 and provides no suggestion to one skilled in the art to modify the process of DE '403 to include calcium phosphate having the claimed pore volume, pore diameter, particle size and BET surface area. Draenert specifically requires the calcium phosphate filler to have a very low porosity of less than 0.1 ml/g that is clearly outside the porosity of the claimed range of 0.4 cm^3/g or more. The material of Draenert relates to a non-biodegradable implant material. The Action provides no basis or rationale for the position that it would have been obvious to one skilled in the art to modify the filler of Draenert in a manner contrary to the specific teachings of Draenert and then modify the process of DE '403. Even if one were to follow the teachings of Draenert and DE '403, the resulting process would not be the claimed invention.

The difference between non-biodegradable implantation materials of Draenert and bioabsorbable composite materials of the present invention are well known in the art as disclosed in column 1, lines 11-17 of Draenert. As disclosed therein, bone cements are not resorbed by the body but are enveloped by the bodies of tissue. Draenert teaches that the implantation materials are not resorbed by the body but are instead enveloped by the tissue after growing into place. Thus, one of ordinary skill in the art would recognize that the implant of Draenert is intended to avoid biodegradation.

Moreover, Draenert expressly teaches the importance of a calcium phosphate having a very low porosity of less than 0.1 ml/g which is clearly outside the claimed range of 0.4 cm^3/g or more. As disclosed in column 4, lines 3-12, the porous tricalcium phosphate has distinct disadvantages. To avoid the complications associated with the porous calcium phosphate, Draenert specifically discloses the use of calcium phosphate having a "very low

porosity *per se*". The pore volume of the materials is disclosed as being below 0.1 ml/g, preferably below 0.05 ml/g. See, for example, column 4, lines 33-38. Column 4, lines 61-64 of Draenert also specifically disclose the pore volume of the tricalcium phosphate being in the range of "0.0 to less than 0.1 ml/g and preferably is 0.0 to below 0.05 ml/g".

In contrast to Draenert, the claimed invention specifically recites the pore volume of 0.4 cm^3/g or more. Thus, the claimed invention recites a pore volume that is four times greater than the upper limit permitted by Draenert. The Action provides no factual basis or rationale to support the assertion that it would have been obvious to one skilled in the art to use calcium phosphate having a pore volume that is well outside the range required by Draenert. Based on the specific teachings of Draenert, one skilled in the art would have no reasonable expectation of success by increasing the pore volume four times the upper limit required by Draenert.

Applicants submit that Draenert effectively teaches away from the claimed invention by disclosing that the bone cements having porosity throughout the cement lack the required stability. See, for example, the paragraph bridging columns 1 and 2. Draenert further discloses that in order to obtain an implantation material having the advantageous properties with respect to the short term and long term stability, the tricalcium phosphate must have a particle size of 50 to 300 μm and an available pore volume of less than 0.1 ml/g. Draenert teaches the use of nonporous tricalcium phosphate providing the improved compressive load bearing ability, a markedly reduced volume shrinkage and improved heat removal during the polymerization process to diminish the heat necrosis. See, for example, column 2, lines 60-68, of Draenert.

Draenert is directed to an implantation material that has a mode of action opposite that of the claimed invention. As noted above, Draenert specifically discloses the disadvantages of the conventional porous tricalcium phosphate that can prevent resorption and avoids these

disadvantages by limiting the pore volume to less than 0.1 ml/g. Draenert provides no suggestion that one skilled in the art would have a reasonable expectation of success in modifying the method of DE '403 in the manner of the claimed invention as asserted in the Action.

Based on the teachings of DE '403 and Draenert, one skilled in the art would readily conclude that a calcium phosphate having a high porosity should be avoided if the resorption of the calcium phosphate is to occur. Applicants submit that the combination of features of claim 1 are not disclosed or suggested in either DE '403 or Draenert. Moreover, based on the specific teachings of Draenert, Applicants respectfully submit that the assertion in the Action that it would have been obvious to modify the process of DE '403 in the manner of the claimed invention is not supported by the art of record and is not supported by any evidence of record or rationale. Accordingly, claim 1 is not obvious over the combination of DE '403 and Draenert.

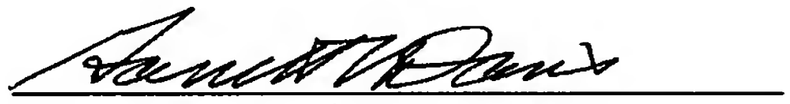
The dependent claims are also not obvious for reciting additional features of the invention that are not disclosed or suggested in the art of record in combination with the features of claim 1. The art of record does not suggest a method of producing a bioabsorbable composite material containing the constituents of claims 2 and 4, the viscosity altering substance of claims 5 and 6, the pH adjusting agent of claims 7 and 9, the adhesion and parting agent of claims 10 and 11, the colorant or contrast agent of claim 12, the active ingredients of claims 13 and 14, the ratio of the bone regeneration materials of claim 15, the bone regeneration material being in powder or granular form of claim 16, forming a solution of the polymerization initiator as in claim 17, the specific polymerization initiators of claims 18 and 19, the step of forming a melt or solution of the polymerization activator as in claim 20, the amount of the polymerization activator of claim 21, the specific polymerization activators of claim 22, the solution of the polymerization initiator of claim 23, the specific

inorganic bone regeneration materials of claim 24, the immobilization of the polymerization initiator and polymerization activator of claims 25 and 26, the pore diameter and particle size of the calcium phosphate as in claims 27 and 28, and the specifically defined calcium phosphate of claim 29 and monomers of claim 31, in combination with the method steps of claim 1.

The art of record also fails to disclose the oligomers or polymeric derivatives of claim 40, the adhesion imparting agent of claim 41, the organic peroxide of claim 42, and the monomers of claim 43, either alone or in combination with the features of claim 1.

In view of these amendments and the above comments, the claims are submitted as being allowable over the art of record. Accordingly, reconsideration and allowance are requested.

Respectfully submitted,



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